

PATENT COOPERATION TREATY

PCT


INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 07 AUG 2006

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Applicant's or agent's file reference P28622WO-PDG E.12715	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US2005/010036	International filing date (day/month/year) 24.03.2005	Priority date (day/month/year) 31.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A61M5/315		
Applicant COOK INCORPORATED et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 31.01.2006	Date of completion of this report 04.08.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Björklund, A Telephone No. +49 89 2399-7310	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

2-18	as originally filed
1, 1a, 1b	received on 02.02.2006 with letter of 31.01.2006

Claims, Numbers

1-11	filed with telefax on 12.06.2006
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Drawings, Sheets

1/6-6/6	as originally filed
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- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 12-25
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10
	No: Claims	11
Inventive step (IS)	Yes: Claims	
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: US-A-4 940 459 (NOCE ET AL) 10 July 1990 (1990-07-10)
- D2: US-A-4 312 343 (LEVEEN ET AL) 26 January 1982 (1982-01-26)
- D3: WO 2004/002375 A (TECRES S.P.A; FACCIOLI, GIOVANNI; SOFFIATTI, RENZO) 8 January 2004 (2004-01-08)
- D4: WO 01/93787 A (COOK INCORPORATED; SABIN CORPORATION) 13 December 2001 (2001-12-13)
- D5: US-A-5 927 562 (HAMMEN ET AL) 27 July 1999 (1999-07-27)
- D6: US 2002/016603 A1 (WELLS TIMOTHY N) 7 February 2002 (2002-02-07)
- D7: WO 95/22941 A (MINNESOTA MINING AND MANUFACTURING COMPANY) 31 August 1995 (1995-08-31)
- D8: US 2002/032447 A1 (WEIKEL STUART ET AL) 14 March 2002 (2002-03-14)
- D9: US-A-3 212 685 (SWAN RICHARD JAMES ET AL) 19 October 1965 (1965-10-19)
- D10: EP-A-0 919 206 (CENTRIX, INC) 2 June 1999 (1999-06-02)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

A high pressure dispenser for the application of a medicinal mixture to a desired location (figs. 1-4), the dispenser comprising:

- a handle (item 22);
- a chamber that receives medicinal mixture coupled to the handle (item 20);
- a threaded region within the handle (item 28);
- a threaded rod in threaded engagement with the threaded region (item 24);
- a knob coupled to the threaded rod (item 46); and
- at least one insert-molded component, wherein the at least one insert-molded component

includes at least one of a threaded insert providing the threaded region insert molded into the handle and a threaded rod insert molded into the knob (col. 4, lines 31-43).

The subject-matter of claim 11 is therefore not new (Article 33(2) PCT)

2.2. Claim 1 contains all the features of claim 11 and should therefore have been drafted as a dependent claim (Rule 6.4 PCT). For examination purposes it will be treated as a dependent claim.

2.3. It is regarded that the difference between claim 1 and the prior art injectors in D2-D4 (see citations in search report), i.e. the insert molded component and metal rod, is trivial as it is known to the person skilled in the art to have an insert molded into plastic (see D5, citations in search report). Therefore, should he want to increase the strength of the threaded parts, he would use a strong insert which would be molded into the knob or the handle. Hence, this standard manufacturing procedure can not render claim 1 inventive (Article 33(3) PCT) over the combinations of the documents D2-D4 with document D5, or even common general knowledge.

3. Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since all the features contained in these claims are not only trivial design options within the common general knowledge of the person skilled in the art but they are also disclosed in D1-D10 (see corresponding passages cited in the search report).

4. The applicants arguments why the claims 1-11 fulfill the requirements of Article 33(1) PCT are not convincing since insert molding other materials (metals) into plastic parts is a standard procedure (see e.g. D5). Furthermore, as defined in claims 11 and 1 the insert molded components do not solve any technical problem since they are not necessarily stronger than the rest of the handle or knob. Consequently, the features of the characterising portions of claims 11 and 1 are merely non-inventive design options.

Re Item VIII

Certain observations on the international application

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5. Claims 1 and 11 have been drafted as independent claims and have at least partly overlapping scope. Drafting such a plurality of independent claims with overlapping scope makes it impossible to clearly delimit the subject matter which could represent the invention for which protection is sought, so that the claims as a whole fail to comply with the clarity and conciseness requirements of Article 6 PCT.

APPARATUS FOR AN IMPROVED HIGH PRESSURE MEDICINAL DISPENSER

REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional application Serial No. 60/558,040, filed on March 31, 2004, entitled "Apparatus for an Improved High Pressure Medicinal Dispenser."

FIELD OF THE INVENTION

[0002] The present invention relates generally to high pressure medicinal dispensers. More particularly, the invention relates to an apparatus for an improved high pressure medicinal dispenser or injector having increased strength and enhanced ergonomic and flow characteristics.

BACKGROUND OF THE INVENTION

[0003] High pressure medicinal dispensers are utilized to inject either fluid or semi-fluid medicinal mixtures under high pressure to desired locations in precisely measured amounts and with only minimal manual force applied. Typically, the high pressure dispenser has a syringe barrel with a cylindrical body and a nozzle at one end, such as disclosed by U.S. Patent No. 4,312,343. A threaded rod may be attached to a knob at one end and a piston at the other. The threaded rod and syringe barrel are commonly held together by a collar. In operation, the knob is utilized to manually rotate the threaded rod, moving the rod into the cylindrical body of the syringe barrel, which allows the piston, attached to one end of the threaded rod, to move the mixture within the cylindrical body of the syringe barrel through the nozzle and to a desired location. Additionally, some conventional designs have a handle interconnected with the syringe barrel.

[0003a] In particular, U.S. Patent No. 4,312,343 describes a syringe comprising a cylindrical barrel with a wall at one end with a nozzle and with a threaded actuating rod extending from its other end. The rod has a piston at the end thereof within the barrel, the piston being in fluid tight engagement with the inner wall of the barrel, and has a knob at its opposite end for rotating the rod.

The rod also carries a collar with threads which mate with the rod threads, and the collar has slots which engage projections on the barrel and prevent movement of the collar relative to the barrel but which permit the collar to be disengaged readily from the barrel. Rotation of the rod causes movement of the piston axially of the barrel when the collar is engaged, but the rod can be moved axially without rotation when the collar is disengaged.

[0003b] Other medical devices include U.S. Patent No. 4,940,459, WO 2004/002375 A1, and WO 01/93787 A2. As reflected by the abstract, U.S. Patent No. 4,940,459 describes an inflation device for a balloon catheter having a pistol grip type handle with a trigger for releasing a screw plunger to enable rapid inflation and deflation of the balloon catheter. The trigger bias and thread angle of mating threads are selected to automatically release the plunger when a safe balloon catheter pressure is exceeded. A trigger guard is slidable over the trigger to prevent accidental operation and pressure release.

[0003c] WO 2004/002375 A1 discloses a device for the manual metering of a medical fluid, such as a hardening resin of the bone cement type, that comprises a chamber for the fluid to be metered (2, 102) with an end opening (6), a gripping handle (7, 107), a piston (10, 110) which is housed in the chamber (2, 102) and provided with an operating member (12) for a user, and screw-type actuating means (13) arranged in between the operating member (12) and the piston (10) so as to perform the longitudinal movement thereof and pressurize the fluid to be metered. The screw means (13) may be modified so as to change from an operative configuration, where the piston is fed micrometrically, to an inoperative configuration, where the piston may move freely. The screw means (13) comprise an outer thread (14, 114) associated with the piston (10) and a female-thread element (15, 115) formed integrally on the handle (7, 107); the handle may be deformed elastically by means of transverse compression so as to change the screw means (13) from their operative configuration to their inoperative configuration.

[0003d] WO 01/93787 A2 discloses a pressure injection syringe (10) with an actuator (100) that includes a plunger (102) for pressurizing viscous fluid material

within a chamber (14). The plunger distal tip (112) includes a high pressure seal (110) defined by a seal member (118) within a seal seat (116). The high pressure seal (110) is viscoselective to permit air passage therepast for aspiration, and to prohibit viscous material passage therepast during actuation of the actuator wherein high pressure is applied to the material within the chamber (14). The viscoselective seal (110) may be defined for example by small axial openings (130) in the seal seat (116) that permit aspiration of air therepast during initial plunger insertion into the chamber, but fluid escape is prohibited by the seal member (118) when the seal member is pressed firmly against a collar (126) of the plunger (102) proximally adjacent the seal seat by initial engagement of the seal member with the viscous material, thus, completely sealing the chamber (14) at the proximal end thereof.

[0004] However, the overall strength of the conventional devices may be limited by the manner in which the individual dispenser components are manufactured and interconnected. The limitations placed upon the strength of the overall conventional devices, as well as the individual high pressure dispenser

WHAT IS CLAIMED IS:

1. A high pressure dispenser for the application of a medicinal mixture to a desired location, the dispenser comprising:
 - a handle (16) formed at least in part of plastics material;
 - a chamber (18) that receives a medicinal mixture coupled to the handle (16);
 - a threaded region within the handle (16);
 - a threaded rod (14) formed of metal and in threaded engagement with the threaded region; and
 - a knob (20) formed at least in part of plastics material coupled to the threaded rod (14);the dispenser characterized in that:
 - the dispenser includes as an insert-molded component a threaded insert (120) providing the threaded region insert-molded into the handle (16) and in that the threaded rod (14) is insert-molded into the knob (20).
2. The dispenser of claim 1, characterized in that the threaded insert (120) includes metal or plastic.
3. The dispenser of claim 1, characterized in that the handle (16) includes hard plastic and overmolded soft rubber.
4. The dispenser of claim 1, characterized in that an exterior surface of the chamber (18) comprises at least one tab (108) dimensioned to engage with at least one
5. The dispenser of claim 1, characterized in that an exterior surface of the chamber (18) comprises at least one notch dimensioned to engage with at least one corresponding tab on an exterior surface of the handle (16).

6. The dispenser of claim 1, characterized in that the handle (16) comprises four exterior longitudinal sides (141, 142).
7. The dispenser of claim 1, characterized in that the knob (20) has an axial length approximately equal to or greater than the diameter of the knob (20).
8. The dispenser of claim 1, characterized in that the knob (20) has at least one longitudinal rectangular cavity (24).
9. The dispenser of claim 1, characterized in that the chamber (18) comprises an interior cylindrical surface (110) and a nozzle (104) in fluid communication, and the interior of the chamber has a concave surface (111) in between the interior cylindrical surface (110) and the nozzle (104).
10. The dispenser of claim 1, characterized in that the threaded rod (14) is coupled to a piston (28), the piston (28) is insert molded into the threaded rod (14).
11. A high pressure dispenser for the application of a medicinal mixture to a desired location, the dispenser comprising:
 - a handle (16);
 - a chamber (18) that receives a medicinal mixture coupled to the handle (16);
 - a threaded region within the handle (16);
 - a threaded rod (14) in threaded engagement with the threaded region; and
 - a knob (20) coupled to the threaded rod (14);the dispenser characterized in that:
 - the dispenser includes at least one insert-molded component, wherein the at least one insert-molded component includes at least one of a threaded insert (120) providing the threaded region insert-molded into the handle (16) and a threaded rod (14) insert-molded into the knob (20).